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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
05/436,066	05/07/95	ENGELHARDT	D ENZ (D5) (C2)

18N2/0415

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EXAMINER	
MARSCHEL, A	
ART UNIT	PAPER NUMBER
1809	29

DATE MAILED: 04/15/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

**Office Action Summary**

Application No.

08/486,066

Applicant(s)

Engelhardt et al.

Examiner

Ardin Marschel

Group Art Unit

1809

☒ Responsive to communication(s) filed on

1/24/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 238-297 and 299-338 is/are pending in the application.

~~Of the above, claim(s)~~ 298 and 1-237 ~~is/are withdrawn from consideration~~ have been canceled

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 238-297 and 299-338 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper Notes~~ 12 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

Applicants' arguments, filed 1/2/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 238, 240-272, 274-297, 299-308, and 310-338 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to "covalent" attachment of the Sig moiety to the sugar (SM) via the hydroxyls at the 2', 3', or 5' positions. This is a relaxation of the previous rejection to include the 5' position labeling. The rejection is thus maintained from the previous office action, mailed 6/25/96, plus the above relaxation due to the persuasive arguments of applicants directed to 5' labeling. Also, the above rejection is necessitated by amendment regarding newly added claims rejected due to their scope being beyond the enabled 2',

3', and 5' SM labeling positions. Applicants also argue the branched sugar nucleoside labeling as broadening the enabled scope. Consideration of this argument reveals that only 2' or 3' labeling is therein discussed which is stated above as being acknowledged as being enabled. RNA labeling is argued but is also acknowledged as instantly enabled due to 2' or 3' labeling. The poly-L-lysine labeling is also at the stated enabled positions on the SM moiety. The phosphate group labeling that is further argued, however, is deemed a PM labeling type that is outside the scope of the instant claims and therefore moot regarding this rejection. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 238-297 and 299-338 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,260,433. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both sets of claims include the SM labeled nucleotide as well as polymers that are SM labeled with a Sig moiety of the same type but the claims are not the same in scope between the claim sets. It is noted that claim 20 of the patent is directed to a polynucleotide. It is additionally noted that applicants have previously submitted a terminal disclaimer regarding said patent but applicants are hereby informed that this was in the parent application to the instant application and does not apply to the instant application. Terminal disclaimers must specifically cite both the instant application in which they are effective as well as the patent/application which is the basis for the disclaimer. This rejection is maintained and necessitated by amendment due to the newly added claims. This rejection has not been argued by applicants.

Enclosed is a copy of the submitted 1449 with several citations lined through. The citation to patent document 255,223 is lined through because it is an application without a publication date. A publication date is required for citation on a 1449. The other references are lined through because no copy was supplied.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

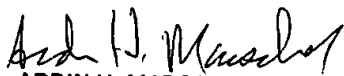
Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

April 11, 1997

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER  
GROUP 1800